

Notice of Allowability	Application No.	Applicant(s)	
	09/869,414	GURNEY ET AL.	
	Examiner	Art Unit	
	Christopher Nichols, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 5 January 2004.
2. ☒ The allowed claim(s) is/are 155-156 and 159-169.
3. ☒ The drawings filed on 27 June 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. The Response and Amendment filed 5 January 2004 has been received and entered in full. Claims 1-154 and 157-158 have been cancelled. Claims 159-162 and 165 have been amended.
2. The Terminal Disclaimer filed 24 March 2004 has been received, entered, and approved.
3. The Information Disclosure Statement filed 24 March 2004 has been received, entered, and taken into consideration.

Withdrawn Objections And/Or Rejections

4. The Objection to the Oath/Declaration as set forth at ¶7 pp. 3-4 in the previous Office Action (5 September 2003) is *withdrawn* in view of Applicant's amendments (5 January 2004).
5. The Rejection of claims **151, 155, 161, and 162** under provisional non-statutory double patenting as set forth at ¶8-9 pp. 4-5 in the previous Office Action (5 September 2003) is *withdrawn* in view of Applicant's amendments (5 January 2004).
6. The Rejection of claims **151-169** under 35 U.S.C. §102(b) as set forth at ¶29-31 pp. 12-13 in the previous Office Action (5 September 2003) is *moot* in view of Applicant's amendments clarifying the priority of the instant application (5 January 2004).

EXAMINER'S AMENDMENT

7. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR

1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

In the Specification:

pp. 28 line 12 add "SEQ ID NO: 69" after "GLALALEP"

In the Claims:

Claims 1-154 (Cancelled)

Claim 155 (Currently Amended) A purified polynucleotide comprising a nucleotide sequence encoding a polypeptide that comprises an amino acid sequence at least 95% identical to a fragment of the Asp2 protein amino acid sequence of ~~Figure 3 (SEQ ID NO: 4)~~ SEQ ID NO: 4 (Figure 3),

wherein said fragment is a continuous fragment of the Asp2 protein that includes the aspartyl protease active site tripeptides DTG and DSG shown in ~~Figure 3~~ SEQ ID NO: 4 and exhibits aspartyl protease activity involved in processing APP into amyloid beta, wherein the polypeptide lacks a transmembrane domain, ~~and~~
~~wherein the polypeptide exhibits aspartyl protease activity involved in processing APP into amyloid beta.~~

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Claim 156 (Previously Presented) A purified polynucleotide comprising a nucleotide sequence that hybridizes under the following stringent hybridization conditions to the complement of SEQ ID NO: 3:

(1) hybridization at 42°C in a hybridization buffer comprising 6x SSC and 0.1% SDS,
and

(2) washing at 65°C in a wash solution comprising 1x SSC and 0.1% SDS;

wherein said nucleotide sequence encodes a polypeptide that lacks a transmembrane domain and exhibits aspartyl protease activity involved in processing APP into amyloid beta.

Claims 157-158 (Cancelled)

Claim 159 (Previously Presented) A purified polynucleotide according to claim 155 or 156, wherein said polynucleotide encodes a polypeptide that includes a heterologous peptide tag.

Claim 160 (Previously Presented) A purified polynucleotide according to claim 155 or 156 that is a cDNA.

Claim 161 (Previously Presented) A vector comprising a polynucleotide of claim 155 or 156.

Claim 162 (Currently Amended) An isolated host cell transformed or transfected with a polynucleotide of claim 155 or 156.

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Claim 163 (Previously Presented) A host cell according to claim 162 that is a mammalian cell.

Claim 164 (Currently Amended) A host cell according to claim 163 ~~derived from~~ that is a human cell line.

Claim 165 (Previously Presented) An expression vector comprising a polynucleotide of claim 155 or 156, wherein the polynucleotide is operably linked to heterologous expression control sequence.

Claim 166 (Currently Amended) An isolated host cell transformed or transfected with the vector of claim 165.

Claim 167 (Previously Presented) A host cell of claim 166 that is a mammalian cell.

Claim 168 (Previously Presented) A vector of claim 165 wherein the polynucleotide is operably linked to a heterologous control sequence for expression in a mammalian host cell.

Claim 169 (Previously Presented) A vector of claim 165, wherein the polynucleotide is operably linked to a heterologous control sequence for expression in an insect host cell.

Claims 170-200 (Cancelled)

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8. Authorization for this examiner's amendment was given in a telephone interview with Sharon Sintich (Reg. No. 48,484) on 22 March 2004.

REASONS FOR ALLOWANCE

9. The following is an examiner's statement of reasons for allowance: Support for the limitation of "in cell culture of a cell-free system" may be found at pp. 51 lines 15-20 of the Specification as filed.
10. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Summary

11. Claims **155, 156, and 159-169** are allowed.
12. The Examiner acknowledges that acceptance of the above Examiner's Amendment does not mitigate in any way, shape, or form, Applicant's right to pursue additional subject matter in continuation, continuation-in-part, and/or divisional applications pursuant to 35 U.S.C. §120 and §121.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is **(571) 272-0889**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on **(571) 272-0887**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

CJN
March 26, 2004


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